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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,229	04/06/2001	Zvia Agur	Q63893	7712

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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,229

Applicant(s)

AGUR ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-167 and 332-349 is/are pending in the application.
- 4a) Of the above claim(s) 118-167 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-117 and 332-349 is/are rejected.
- 7) ☒ Claim(s) 66-69, 75, 82, 92-95, 101, 102, 332-335 and 341-344 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Applicant's election without traverse of Group I, claims 66-117 and 332-349 in Paper No. 8, filed 1/24/03 is acknowledged.

Claims 118-167 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

An action on the merits of elected claims 66-117 and 332-349 follows.

Information Disclosure Statement

Applicant is reminded of the duty to disclose to the Office all information known to that individual to be material to patentability, as set forth under 37 CFR 1.56. It is noted that numerous references are cited throughout the specification; however, no IDS has been received by the examiner as of the date of this office action.

Applicant is advised that listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: there is no compartment labeled 30, 40, 50, 60, 70, 80, 90, or 100 in Figure 3. Further, there is no "line 31" or any compartment labeled "PL" in Figure 3, as disclosed on pages 82-85 of the specification.

The drawings are also objected to under 37 CFR 1.83(a) because Figure 3 fails to show "age sections" as described in the specification. Page 86 of the specification discloses "age sections" in the MKB compartment of Figure 3. However, the sections in the MKB compartment of Figure 3 appear to be

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sections which show progression of ploidy (2N, 4N, etc.), not age. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

The drawings are further objected to because Figure 7 has no Figure legends, and is therefore incomprehensible. Similarly, the Figure legends for Figures 8 and 9 refer to colors. As Figures 8 and 9 are not rendered in color, the Figure legends are nonsensical, and Figures 8 and 9 are also incomprehensible. Proposed drawing corrections or corrected drawings are required in reply to this Office action to avoid abandonment of the application. The objections to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: there is no "Brief Description" of Figure 2b on page 71. Appropriate correction is required.

The abstract of the disclosure is objected to because it does not specifically describe the subject matter of the elected claims. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 66-69, 75, 82, 92-95, 101, 102, 332-335, 341-344 are objected to because of the following informalities: in claims 66-69, 92-95, 332-335, 341, and 343-344, the terms "Thrombopoietic", "Thrombopoiesis", and "Thrombocytopenia" should be -- thrombopoietic--, --thrombopoiesis--, and -- thrombocytopenia-- . In claims 75 and 101, the term "a" beginning each of lines 11, 15, 18, and 21 should be --an--. In claims 82 and 108, the term --on-- should be inserted after "based" in line 2 of each claim. In claim 102, the term "are" after "apoptosis" in line 1 should be --is--. In claims 333 and 342, the term "indiseased" in line 2 of each should be --in diseased--. In line 2 of claim 342, the term "throbmopoiesis" should be --thrombopoiesis--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Examiner's note: The terms "contains", "containing", "include", "including", and any other bridging term which is not specifically defined in the specification recited in the claims is interpreted by the examiner to be open claim language, equivalent to "comprises" or "comprising".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-117 and 332-349 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 recites the phrase "realistic process progression model". Claims 67, 69, 93, 95, 333, 335, 342, and 344 recite the phrase "realistic progression of cells". Claim 92 recites the phrase "realistic process model". Claims 332 and 341 recite a step of "realistically modeling a process". It is unclear what limitations applicant intends for a "realistic" progression of cells or for a "realistic" model, or for "realistically" modeling a process, therefore the claims are indefinite. It is noted that various limitations of a "process model" are recited in dependant claims (e.g. 72, 74), however, it is not clear whether these limitations are those which render the model "realistic". The specification discloses on page 72 that complex mathematical descriptions (i.e. using heuristics to find solutions to a variety of scenarios) "are contemplated to be realistic simulations of actual scenarios." Given this disclosure and the disclosure on at least page 7 of the specification that at least one embodiment of the invention is a "realistic biological process model", the mathematical model described on pages 82-114 of the specification is considered by the examiner to be an example of a "realistic" process model, and the method of using the model is considered to be one of "realistically modeling" a process, therefore these limitations are adequately described by the specification. Further, although the specification does not specifically describe the cell progression in the mathematical model as a "realistic progression of cells", the examiner interprets the detailed progression described on pages 97-109 to be an adequate description of a "realistic progression"

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of cells within the model. Applicant is reminded that limitations from the specification can not be "read into" the claims. Thus, while the instant specification does appear to describe a "realistic" process model, a "realistic" progress of cells, and steps of "realistically" modeling a process, the description of these are not limitations of the claims. As the goal of a biological model is to duplicate or predict "real-life" events, every model of a biological process may be said to be "realistic" on some level, therefore there is a vast range of what is defined to be "realistic" in the biological modeling art. As one skilled in the art would not know what limitations applicant intends as the metes and bounds of a "realistic" model, step, or progression, the claims are indefinite.

Claims 70, 96, 336, and 345 recite the capitalized terms "Thrombopoietin". Due to the use of a capitalized term, it is unclear if applicant intends --thrombopoietin--, or intends a trademarked product or a product with the trade name "Thrombopoietin", therefore the claim is indefinite. Applicant is reminded that the use of trademarks and/or tradenames in a claim renders the claim indefinite.

Claims 67, 69, 72, 77, 93, 95, 98, 103, 338, and 347 recite the term "incorporates". It is unclear if applicant intends the term to be a verb, or intends the term to be equivalent to --comprises--. As the meaning intended by applicant is unclear, the claims are indefinite.

Further, with regard to claims 67, 69, 72, 77, 93, 95, 98, and 103, these claims are directed toward systems (i.e. products), not methods. If "incorporates" is intended to be a verb, then these claims appear to be directed to method steps (e.g. a step of incorporating a realistic progression of cells, effects, etc. into a model). As it is unclear whether applicant intends a method step, or intends a limitation of a system, the claims are further indefinite.

Claims 71, 97 recite the term "imitates". Claims 71, 97 are directed toward systems (i.e. products), not methods. However, use of an active verb makes it unclear whether applicant intends a method step (e.g. a step of imitating), or intends a limitation of a system, therefore the claims are indefinite.

Claims 72 and 338 each recites the term "the patient" in line 2. There is no antecedent basis for this term in the claims, therefore the claims are indefinite. It is noted that parent claims 66 and 332

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recite "an individual", therefore this rejection may be overcome by replacing "patient" with --individual-- in line 2 of each claim.

Claim 72 recites the term "administration" with regard to a patient in line 2. This appears to be a method step. As it is unclear whether applicant intends a method step (e.g. a step of administering), or intends a limitation of a system, the claims are indefinite.

Claim 73 recites the phrase "can be". The use of this phrase renders it unclear whether the limitations following the phrase are actual limitations of the claim, therefore the claim is indefinite. This rejection may be overcome by replacing "can be" with a definite term, such as --is--.

Claims 75, 101 limit a process model in a system (a product) to comprise specific compartments wherein cells apparently perform specific acts. For example, cells in the compartments are limited to: proliferate and differentiate; get committed... and spend some time multiplying and maturing; release/do not release platelets, exhaust...capacity, are disintegrated, and continue with endomitosis. A model may comprise cells capable of these functions or may model these functions, but a model does not generally comprise the cells themselves which perform these functions (i.e. the physical acts themselves do not occur within the model). As it is unclear what limitations of the model/system applicant intends by recitations of the various cell functions/acts, the claims are indefinite.

Claims 75, 101 recites cells which release platelets "until they exhaust their capacity" in a limitation of the MK16 compartment. It is unclear whether it is the cell or the platelets "which exhaust their capacity", therefore the claims are indefinite. Further, it is unclear what the "capacity" is which is exhausted, therefore the claims are further indefinite.

Claims 76, 101 recite that an effect "is included" or "are included" with another effect in "giving rise" to cell amplification. It is noted that the claims are drawn to a system (product), but appear to be reciting method steps. As it is unclear what limitation of the system applicant intends, the claims are indefinite.

Claims 81-83, 107-109 recite the term "transit time". It is unclear what is "transiting"; i.e. a compartment (and if a compartment, where or to what the compartment is "transiting"), a cell through a compartment, or some other factor, therefore the claims are indefinite. If applicant intends a transit time

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of a cell through a compartment, then this rejection may be overcome by inserting --of a cell-- or --of cells-- after each recitation of "transit time" in the claims.

Claims 91 and 117 recite the phrase "is used" with regard to a model. The phrase "is used" indicates that the claims are methods of use; however, the claims are also clearly directed to systems (products). It is unclear whether applicant actually intends the claims to be directed to methods or products, therefore the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92-94, 97, 100, 114, 341-343, and 346 are rejected under 35 U.S.C. 102(b) as being anticipated by WICHMANN et al. (Cell Tissue Kinetics (1979) vol. 12, pp. 551-567).

WICHMANN teaches a system and method of predicting/modeling thrombopoietic lineage in rats wherein his model comprises a "realistic" progression of cells, specifically through compartments S, M, P, and T (pages 553-554), thereby anticipating claims 92, 100, and 341. WICHMANN teaches that his method may be used to model cells involved in thrombocytopenia (pp. 555-556), thereby anticipating claims 93-94 and 342-343. WICHMANN further teaches that the cells in his compartments may be subdivided into cells of specific ages (pp. 553-554), thereby anticipating claim 114. WICHMANN also teaches that experimental data regarding stem cell proliferation (i.e. bone marrow progression), platelet counts, and TPO concentration changes may be included in his model (p. 555, Table 1), thereby anticipating claims 97 and 346.

Claims 92-96, 100 and 341-344 are rejected under 35 U.S.C. 102(b) as being anticipated by KLIEM et al. (Experimental Hematology (1997) vol. 25 (8), pp.899).

KLIEM teaches a system/method for modeling/predicting thrombopoietic lineage in mice wherein his system describes in vivo responses, and is therefore "realistic", and thus anticipates claims 92 and 342. KLIEM teaches that his system/method can be used to model thrombocytopenia, comprises data with regard to compartments and transit time of cells (i.e. cell progression), and incorporates the effects of PEG-rHuMGDF administration, thereby anticipating claims 93-96, 100, and 342-344.

Conclusion

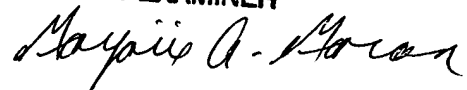
No claims are allowed; claims 118-167 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER



mam
April 4, 2003